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Pralidoxime Chloride for Injection

DEFINITION

Pralidoxime Chloride for Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of pralidoxime chloride ($C_7H_9ClN_2O$).

IDENTIFICATION

Change to read:

- **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197A, 197K, or 197M▲ (CN 1-May-2020)
- **B.** Identification Tests—General ⟨191⟩, *Chemical Identification Tests*, *Chloride*: A solution (1 in 10) meets the requirements.
- **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Solution A: Prepare a solution containing 8 mM sodium octanesulfonate and 2 mM tetraethylammonium chloride as follows. Transfer 1.87 g of sodium octanesulfonate monohydrate and 330 mg of tetraethylammonium chloride to a 1-L volumetric flask, add water to dissolve the mixture, and dilute with water to volume. Adjust with 0.01 N hydrochloric acid to a pH of 4.3.

Mobile phase: Acetonitrile and *Solution A* (17:83)

Diluent: Acetonitrile and water (17:83)

Standard stock solution: 1.25 mg/mL of USP Pralidoxime Chloride RS in water. Use sonication to dissolve, if necessary.

Standard solution: 0.125 mg/mL of USP Pralidoxime Chloride RS in *Diluent* from the *Standard stock solution*

Sample stock solution: Nominally 1.25 mg/mL of pralidoxime chloride prepared as follows. Select a number of containers of Pralidoxime Chloride for Injection, the combined contents of which are equivalent to about 10 g of pralidoxime chloride. Dissolve the contents of each container in water and combine all of the solutions in a 1000-mL volumetric flask. Rinse each container with water and add the rinsings to the volumetric flask. Dilute with water to volume and mix. Transfer 25.0 mL of the resulting solution to a 200-mL volumetric flask and dilute with water to volume.

Sample solution: Nominally 0.125 mg/mL of pralidoxime chloride in *Diluent* from the *Sample stock solution*. [Note—This solution is stable for up to 6 h when stored at room temperature protected from light.]

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 15-cm; 3- or 3.5-µm packing L1

Flow rate: 0.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—USP Pralidoxime Chloride RS contains pralidoxime *anti*-isomer as a minor component. The relative retention times for pralidoxime *anti*-isomer and pralidoxime are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the pralidoxime *anti*-isomer and pralidoxime peaks

Tailing factor: NMT 1.5 for the pralidoxime chloride peak

Relative standard deviation: NMT 1.0% for the pralidoxime chloride peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pralidoxime chloride ($C_7H_9ClN_2O$) in the portion of Pralidoxime Chloride for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of pralidoxime from the *Sample solution*

r_S = peak response of pralidoxime from the *Standard solution*

C_S = concentration of USP Pralidoxime Chloride RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of pralidoxime chloride in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

IMPURITIES

• **Organic Impurities**

Solution A, Mobile phase, Diluent, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard stock solution: Use the *Standard solution* prepared as directed in the *Assay*.

Standard solution: 0.125 µg/mL of USP Pralidoxime Chloride RS in *Diluent* from the *Standard stock solution*

System suitability

Samples: *Standard stock solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between the pralidoxime *anti*-isomer and pralidoxime peaks, *Standard stock solution*

Relative standard deviation: NMT 5.0% for the pralidoxime chloride peak, *Standard solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each impurity in the portion of Pralidoxime Chloride for Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of pralidoxime from the *Standard solution*

C_S = concentration of USP Pralidoxime Chloride RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of pralidoxime chloride in the *Sample solution* (µg/mL)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Pyridine-2-aldoxime	0.7	0.5
Pralidoxime *anti*-isomer[a]	0.9	2
Pralidoxime	1.0	—
Any other individual impurity	—	0.2
Total impurities	—	3

[a] (*Z*)-2-[(Hydroxyimino)methyl]-1-methylpyridin-1-ium chloride.

SPECIFIC TESTS

• **Constituted Solution:** At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Product Quality Tests Common to Parenteral Dosage Forms, Specific Tests, Completeness and clarity of solutions*

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.10 USP Endotoxin Units/mg of pralidoxime chloride.

• **pH ⟨791⟩:** 3.5–4.5, in a solution (1 in 20)

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 2.0%

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Other Requirements:** It meets the requirements for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*.

• **USP Reference Standards ⟨11⟩**

USP Pralidoxime Chloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PRALIDOXIME CHLORIDE FOR INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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